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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/482,788 01/13/00 BERKA

R 5778.200-US

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HM12/0327

EXAMINER

TUNG, P  
ART UNIT PAPER NUMBER

1652  
DATE MAILED:

03/27/01

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

|                              |                                      |                                     |
|------------------------------|--------------------------------------|-------------------------------------|
| <b>Office Action Summary</b> | Application No.<br><b>09/482,788</b> | Applicant(s)<br><b>Berka et al.</b> |
|                              | Examiner<br><b>Peter Tung</b>        | Group Art Unit<br><b>1652</b>       |

Responsive to communication(s) filed on \_\_\_\_\_.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-3, 8, 9, 13, 22-24, 30, 31, 37, 42, 50, 53, 57-59, 63, and 64 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) \_\_\_\_\_ is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 1-3, 8, 9, 13, 22-24, 30, 31, 37, 42, 50, 53, 57-59, 63 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-3, 8, 9 and 13, drawn to a method for producing a heterologous polypeptide using a mutant filamentous fungal cell, classified in class 435, subclass 69.1.
- II. Claims 22-24, drawn to a mutant cyclohexadepsipeptide-deficient mutant filamentous fungal cell, classified in class 435, subclass 254.11.
- III. Claims 30, 31, 37, 42 and 50, drawn to a cyclohexadepsipeptide synthetase, classified in class 435, subclass 183.
- IV. Claims 53, 57-59, 63 and 64, drawn to DNA encoding a cyclohexadepsipeptide synthetase, vectors, transformed host cells and a method of making said cyclohexadepsipeptide synthetase, classified in class 435, subclass 183.

2. The inventions are distinct, each from the other because of the following reasons:

Each of Groups II, III and IV is directed to a separate and distinct invention. Group II is directed to a mutant cyclohexadepsipeptide-deficient mutant filamentous fungal cell, Group III is directed toward a cyclohexadepsipeptide synthetase and transformed hosts and Group IV is directed toward DNA encoding a cyclohexadepsipeptide synthetase, vectors and transformed host cells.

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The products of Group II, III and IV would be expected to have distinct morphological, functional, chemical and physical properties as indicated by their divergent classification, process of making and process of using. These products are capable of separate manufacture, use, or sale as claimed, and are patentably distinct.

3. Each of Groups I, II and III is directed to a separate and distinct invention. Group I is directed to a method producing a heterologous polypeptide using a mutant filamentous fungal cell and Group IV is directed to a method of a method of making cyclohexadepsipeptide synthetase. These methods are distinct both physically and functionally, require different process steps, reagents and parameters and produce different products.

4. Inventions of Group IV and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by a different process such as by peptide synthesis.

5. Inventions of Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product can be practiced with a different product such as expression of proteins in yeasts.

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6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Tung, Ph.D. whose telephone number is (703) 308-9436. The examiner can normally be reached on Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, Ph.D., can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-0294.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



PONNATHAPU ACHUTAMURTHY  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600